[6750-01-P]

FEDERAL TRADE COMMISSION

[File No. 192 3088]

BASF SE and DIEM Labs; Analysis of Proposed Consent Orders to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement; Request for Comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis of Proposed Consent Orders to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent orders—embodied in the consent agreements—that would settle these allegations.

DATES: Comments must be received on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write "BASF SE; File No. 192 3088" on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Janet Evans (202-326-2125), Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR § 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreements and the allegations in the complaint. An electronic copy of the full text of the consent agreement packages can be obtained at https://www.ftc.gov/news-events/commission-actions.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]. Write "BASF SE; File No. 192 3088" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Due to the COVID-19 public health emergency and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write "BASF SE; File No. 192 3088" on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street

SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov*, you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the *https://www.regulations.gov* website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a

confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC Website at http://www.ftc.gov to read this Notice and the news release describing the proposed settlement. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see https://www.ftc.gov/site-information/privacy-policy.

Analysis of Proposed Consent Orders to Aid Public Comment

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a consent order with BASF SE and BASF Corporation ("BASF Respondents"). It also has accepted, subject to final approval, an agreement containing a consent order with DIEM Labs, LLC, and others ("DIEM Respondents"). The proposed consent orders have been placed on the public record for 30 days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreements and the comments received, and will decide whether it should withdraw from one or both of the agreements and take appropriate actions, or make final the agreements' proposed orders.

This matter involves Respondents' advertising for Hepaxa and Hepaxa PD capsules containing omega-3 fatty acids. The Commission's proposed complaint alleges that advertising for the Hepaxa products represented that Hepaxa reduces liver fat in most adults with Nonalcoholic Fatty Liver Disease ("NAFLD") within six months, and that Hepaxa PD reduces liver fat in most children with NAFLD within six months. The

complaint further alleges that Respondents' advertising represented that tests prove that Hepaxa reduces liver fat in adults with NAFLD and that tests prove that Hepaxa PD reduces liver fat in children with NAFLD. According to the proposed complaint, these claims are false or misleading, or were not substantiated at the time the representations were made, in violation of Sections 5 and 12 of the FTC Act.

The proposed orders include injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The proposed orders against the BASF Respondents and DIEM Respondents are substantially similar. In both orders, "Covered Products" is defined as Hepaxa, Hepaxa PD, and any other Dietary Supplement, Food, or Drug that contains one or more omega-3 fatty acids or is promoted by a Respondent or its subsidiary to benefit cardiac, metabolic, or hepatic health or functions, including the prevention, mitigation, treatment, or cure of any disease of such systems.

Part I of the orders prohibits Respondents from making any representation that a Covered Product reduces liver fat in adults or children with Non-alcoholic Fatty Liver Disease (NAFLD), or cures, mitigates, or treats any disease, including but not limited to liver disease, unless the representation is nonmisleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part I, competent and reliable scientific evidence must consist of human clinical testing of the covered product, or of an essentially equivalent product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.

Part II prohibits Respondents from making any representation, other than representations covered under Part I, about the health benefits, performance, efficacy, safety, or side effects of any covered product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of Part II, "competent and reliable scientific evidence" means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, or of an essentially equivalent product, when such experts would generally require such human clinical testing to substantiate that the representation is true.

Part III prohibits misrepresentations about tests and studies. Part IV provides Respondents a safe harbor for making claims approved by the Food and Drug Administration ("FDA"). Part V requires that, with regard to any human clinical test or study upon which Respondents rely to substantiate any claim covered by the orders, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of a test.

Part VI provides for monetary relief, and Part VII describes the procedures and legal rights related those payments. Together, Respondents are paying the full amount of consumer injury, $416,914.00. DIEM Order Part VIII requires the company to provide

sufficient customer information to enable the Commission to efficiently administer consumer redress to purchasers of Hepaxa and Hepaxa PD.

DIEM Order Part IX and BASF Order Part VIII require Respondents to submit acknowledgments of receipts of the order. DIEM Order Part X and BASF Order Part IX require the filing of compliance reports with the Commission, including notification to the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. DIEM Order Part XI and BASF Order Part X contain recordkeeping requirements. DIEM Order Part XII and BASF Order XI contain other requirements related to the Commission's monitoring of Respondents' order compliance. Finally, DIEM Order Part XIII and BASF Order Part XII state that the orders will remain in effect for 20 years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the orders, and it is not intended to constitute an official interpretation of the complaint or orders, or to modify the orders' terms in any way.

By direction of the Commission.

April J. Tabor,

Secretary.

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